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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MENON, KRISHNAN S	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,340	PEDRAZZI, RENATO	
	Examiner	Art Unit	
	Krishnan S Menon	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-47 and 50-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24,31,33-35,41-46,50-59* is/are rejected.

7)☒ Claim(s) *25-30,32,36-40 and 47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 22-47 and 50-59 are pending after the amendment of 12/29/04

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 53-59 are rejected under the judicially created doctrine of double patenting over claims 1,9-11,14 and 15 of U. S. Patent No. 6,730,233 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: instant claims recite a blood treatment apparatus whereas the patent claims a dialysis machine. A dialysis machine is a blood treatment apparatus. Moreover, the claimed limitations in the instant claims have only minor, obvious variations with respect to the claims of the patent. The apparatus recited is structurally similar to the machine claimed in the patent. Limitations such as '..control

unit configured to control.. (or 'regulate) ... operating conditions...' are only functional language, which would not make the claims patentable.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 22-23, 43 and 51-59 are rejected under 35 U.S.C. 102(b) as being anticipated by English translated copy of WO 98/50091 (hereinafter referred to as WO translation).

WO translation teaches a blood purification device comprising electronic control means (9-14) which based on measurements from pressure gauges 27-3'-4' and balances 5-6-7 to steer flows applied by pumps 1-4 including a pump (2) for replacement fluid i.e. infusion liquid wherein replacement fluid is brought by means of pump (2) from receptacle (15) with a flow divider regulating/controlling the proportion between the flow of replacement fluid injected into the blood circulation upstream from the filtration means (8) and the flow of replacement fluid injected into the blood

circulation downstream from the filtration means (8) (see figure, page 11, 2nd and 4th paragraphs). WO translation further teaches pumps (2, 3) for circulating infusion liquid in pre dilution and post dilution pipes (see figure).

Claims 51,52,54: WO translation teaches an infusion control device having an infusion circuit (see the flow diagram) comprising a pre-dilution pipe (line 25), a post dilution pipe (from pump 3), and a control unit ((9-12), wherein the control unit is configured to determine/control/regulate the flow rates in the pipes by at least the filtration factor of the membrane (ultrafiltrate extracted), permeability of the membrane (from ultrafiltrate measurement) or trans-membrane pressure (see at 3,4,6,7,12).

Claims 53 and 55-59: WO translation teaches a blood treatment apparatus comprising a filter having a blood compartment and a liquid compartment separated by a semipermeable membrane (8), an arterial pipe (20), a venous pipe (210, a drain pipe (24), an infusion circuit with pre and post dilution pipes (25 and at pump 3), and a control unit (9-12). Control unit is configured to control/regulate/determine distribution of infusion flow rates based on at least the membrane permeability or the trans-membrane pressure (see at 3,4,6,7,12).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 24, 31, 33 (independently), 35, 41 (independently), 42, 44, 45 (independently), 46, 50 (independently), are rejected under 35 U.S.C. 103(a) as being unpatentable over WO translation as applied to claim 22 as above, and further in view of U.S. Patent No. 5,762,805 (hereinafter referred to as Truitt et al).

WO translation teaches the blood purification device as described in above paragraph 2. Claims 24, 31, 33 (independently), 35, 41 (independently), 42, 44, 45 (independently) and 46 essentially differ from the device of WO translation in reciting monitoring trans-membrane pressure values and the actual permeability of a membrane of a filter. Truitt et al teach a device for extracorporeal purification of blood comprising a blood filtration unit (40) comprising pressure sensors (51, 53, 54, 84) for measuring trans-filter pressure or trans-membrane pressure i.e. a parameter influenced by the resistance of the filtration unit (40) to the flow of liquid (see figures 1-2, col. 3, line 59 - col. 6, line 20), a computation unit comprising a control unit (102) connected to a monitor unit (104) for monitoring pressure sensors (51, 53, 54, 84) and for controlling a pump (66) for controlling the substitution solution to flow in a connecting conduit (70) (see figures 3a-3b, col. 6, line 43 - col. 11, line 40) wherein the control processor (122) in the control unit (102) receives signals from the monitor processor (140) in the monitor unit (104) and transmits signals to a motor controller (128) to halt a pump (66) whenever pressure sensors (51, 53, 54, 84) signal an abnormal pressure value from predetermined stored pressure value and allows operator to adjust the treatment steps to continue the treatment (see col. 17, line 31 - col. 18, line 27; col. 16, lines 10-40). It would have been obvious to a person of ordinary skill in the art at the time the invention

was made to incorporate pressure sensors of Truitt et al to measure trans-filter pressure which indirectly measures the permeability of the filter in the device of WO translation to improve the control of infusion of liquid.

With regard to claim 50, Truitt teaches determining the infusion flow rate based on at least the filtration factor or the trans-membrane pressure.

3. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO translation in view of Truitt et al as applied to claim 33 in above paragraph 4, and further in view of WO 00/09182 (hereinafter referred to as WO '182).

WO translation in view of Truitt et al teaches the blood purification device as described in above paragraph 4. Claim 34 essentially differs from the device of WO translation in view of Truitt et al in reciting a valve means for alternatively occluding the pre-dilution pipe and the post-dilution pipe. WO '182 teaches a blood purification device comprising valves (3, 4) for controlling the fluid to upstream and downstream of the filter (see abstract; figure 7). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate valves of WO '182 to control the flow of fluid into the pre dilution pipe and the post dilution pipe in the device of WO translation in view of Truitt et al.

Allowable Subject Matter

Claims 25-30, 32, 36-40 and 47 would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 12/29/04 have been fully considered but they are not persuasive.

In response to the arguments re the 102(b) rejection of claims 22,23 and 43: The amendment to the claims seem to be only cosmetic. The control unit in the WO translation is configured to control the parameters by regulating flows as described in the reference at various cited paragraphs. Applicants need to elaborate on how the WO translation fails to teach 'controlling the distribution of the infusion flow rate in arterial and venous pipes', and how is it different in the applicants' invention. Translation at 6 generically describes this 'distribution of infusion flow rates' when it teaches 'adjust the instantaneous flows of ... blood, ultrafiltrate and substitution products' by electronic control means parameters established for the treatment and variables measured by gauges.

With re to the argument about the Truitt ref that it also does not teach the 'distribution of infusion flow rates', see Truitt abstract. The teaching "A replacement fluid is selectively and controllably added to the blood, as required for the selected treatment. A secondary fluid is controllably and selectively introduced into the secondary chamber of the filtration unit for controllably collecting material passing across the semipermeable membrane from the blood or for supplying material to pass across the semipermeable membrane into the blood as required for the selected treatment." Shows such controlling of the distribution of flows in the arterial and venous

pipes. The flow distribution in the arterial and venous pipes change in a controlled manner by the controlled addition or removal of fluids.

Argument re claim 33: all the limitations of claim 33 are taught by WO translation except for the controller being configured to ...correlate with the blood concentration or filtration efficiency, which is taught by Truitt.

Rest of the arguments do not specifically point out what element(s) in the claims are missing in the combination of the references, or how the combination is inappropriate.

Regarding claims 50-59,new claim 51 does not correspond to any of the cancelled claims because the cancelled claims 48 and 49 are directed to process, 51 is an apparatus. Claim 50 does not correspond to any of the claims that were indicated as allowable. With re to the claims 52-59, the claims are anticipated by WO translation as shown in the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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